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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/483,504	01/14/2000	Min Teng	5686.200-US	8481

23650 7590 07/06/2004

NOVO NORDISK PHARMACEUTICALS, INC  
100 COLLEGE ROAD WEST  
PRINCETON, NY 08540

EXAMINER
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PATEL, SUDHAKER B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 07/06/2004

*Restart office action  
dated 11-19-03.*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/483,504

Applicant(s)

TENG ET AL.

Examiner

Sudhaker B. Patel, D.Sc. Tech.

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 37, 52, 53 and 65-70 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 37, 52, 53 and 65-70 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other:

### DETAILED ACTION

Applicants' communication paper # 12 dated 10/9/03 is acknowledged.

Applicants have cancelled claims 2-36,38-51, 54-64, amended claims 1,37,52,53,65,66, and presented new claims 67-70. Therefore, the claims in this application are the claims 1,37,52,53,65-70.

After further review and reconsideration this application is found not ready for allowance at this stage for reasons stated below. e.g. various intermediates as claimed herein are not excluded by the proviso, and the claim1 encompasses compounds already known in prior art(s). See enclosed copies of the Chemical Abstracts with this communication and additionally, 35 U.S.C. 102(b) rejections. (1) Chemical Abstr. DN 103:37081 with CASRN # 97183-62-5;(2) Chem.Abstr. DN 92 :76440 with CASRN # 52312-40-0; (3) Chemical Abstr. DN 117:192207 with CASRN # 143309-87-9;(4) Chem.Abstr. DN 75:129758 with CASRN # 33870-76-7 & 3380-77-8;(5) Chemical Abstr. DN 109:92044 with CASRN # 6640-47-7;CASRN#90004-55-0;(6) Chemical Abstr. DN 115:70795 with CASRN# 34972-22-0;(7) Chemical Abstr. DN 128:75375 with CASRN #6640-47-7 & 200815-10-7;(8) Chemical Abstr., DN 112:179028 with CASRN 126444-88-0, CASRN# 126444-89-1,CASRN# 126444-90-4, CASRN# 126444-91-5, CASRN# 126444-92-6)

### ***Election/Restrictions***

1. Applicants' election without traverse of invention of Group III in their paper #9 dated 3/17/03 is made FINAL.
2. Rejections withdrawn:

2.1. The rejection made under 35 U.S.C. 102(b) has been made moot by applicants' amendments to claim 1 to delete that L can be a valence bond. Therefore, the same has been now withdrawn.

2.2. Applicants' above stated cancellation, amendments and presentation of new claims together with their arguments and remarks are sufficient for the withdrawal of rejections made under 35 U.S.C. 112 paragraph second. Therefore, the same have been now withdrawn.

3. New Rejections:

***Claim Rejections - 35 USC § 112***

3.1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and dependent claims 37, 52, 53, 65-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A). Amended claims 1, 37 recite component(s) as heteroaryl, e.g. R9. The claims remain silent about the number nature and exact make up of heteroatoms, the exact ring size, their exact point of connection with the N of the bridge when present. Specification on page 7 defines "Heteroaryl", which also includes the partially hydrogenated derivatives in addition to "optional substituents" as outlined in the claim 1.

The claims do not exactly state the heterocycles excluded, and this will raise additional issues related to patentable distinction of the novelty. Recitation of the compounds of invention of Group III already made and tested from the examples

actually made in specification pages 55-171 is required. See rejections under 35 U.S.C. 102(B) and allowable subject matter bellow.

(B). Amended Claim 65 recited as: "A method of the treatment of disorders or diseases wherein an activation of the human GFLP-1 receptor is beneficial", is not a single disease or disorder. Recitation of specific disease(s) as per the tests conducted (see specification page 166) is required. e.g. decrease in weight in patients with Type 2 diabetes.

***Claim Rejections - 35 USC § 102***

3.2 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(1). Claims 1, 37,52,53,65-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Bata et al (WO9719934, also cited as CAPLUS DN 127:95295)).

The ref.'934 teaches compounds with CAS RN #: 1). CASRN # 192075-86-8(= 2,3-QUINOXALINEDIAMINE, 6,7-DICHLORO-);2). CASRN# 192075-88-0(= 2,3-Quinoxalinediamine, 5,7-dichloro-;3). CASRN# 192075-91-5(= 2(1H0-quinoxalinethione,3-amino-6-chloro-7-(trifluoromethyl)-, which is equivalent to its thiol (= -SH) tautomeric form(s) as claimed herein;4). CASRN# 192075-92-6(= 2(1H)-quinoxaline thione, 6-chloro-3- (methylamino)-7-(trifluoromethyl)-;5).CASRN# 192076-03-2(=2(1H)-Quinoxalinethione,3-amino-7-chloro-

6-(trifluoromethyl)-; 6). CASRN# 19076-04-3(= 2(1H)-quinoxalinethione,7-chloro-3-(methylamino)-6-(trifluoromethyl)-.

(2). Claims 1, 37,52,53,65-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Sam et al(U.S.P. 4022777, also cited as Chemical Abstract DN 87:68423 with a list of several patent family numbers).

Sam teaches compounds with CASRN #: 1).CASRN# 52312-43-3(=Acetamide, N-(3-amino-2-quinoxaliny)-;2). CASRN# 52312-40-0(=2,3-quinoxalinediamine,6-chloro-;3). CASRN# 52312-41-1(=2,3-Quinoxalinediamine,6-fluoro-;4).CASRN#52312-42-2(=2,3-Quninoxalinediamine,6-bromo-.

(3). Claims 1, 37,52,53,65-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Wozniak et al(Indian J. of Heterocyclic Chem.,4/2,75-80(1994)).

Wozniak teaches making of compound with CASRN: 1). CASRN# 163388-61-2(= 2,3-quinoxalinediamine, N,N'-dimethyl-6-nitro-;2). CASRN# 163388-62-3(= 2,3-quinoxalinediamine,N2-methyl-6-nitro;3). CASRN# 163388-63-4(=2,3-quinoxalinediamine,N3-methyl-6-nitro-.

(4). Claims 1, 37,52,53,65-70 are rejected under 35 U.S.C. 102(b) as being anticipated by Kyowa et al(JP 55167205, also cited as Chemical Abstract DN 94:169423).

Kyowa teaches making of compounds with CASRN: 1).77186-60-8(=2-quinoxalinamine,N-ethyl-3-methyl-;2).CASRN# 77186-61-9(=2-quinoxalinamine,3-methyl-N-propyl)-;3). CASRN# 77186-63-1(=2-quinoxalinamine,N,3-diethyl-;4). CASRN# 77186-64-2(=2-quinoxalinamine,3-ethyl-N-propyl-.

**Conclusion**

**Allowable Subject Matter**

4. Claims 1, 37, 52, 53 related to compounds & composition would be allowable for the subject matter of invention of Group III( wherein the variables are as species of Example 103, the component -NR9 has specification and exact R9 component from the species made, and the intermediates not included in the references cited above), if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph and other rejections, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 65-70 related to method of use of the compounds of invention of Group III would be also considered for allowance, if limited to a single disease, and also rewritten to overcome the rejections as stated above in this communication.

4.1. The following is a statement of reasons for the indication of allowable subject matter: The closest prior art(s)ref. Englehardt et al(DE 2433397) teaches Quinoxaline, 6,7-dichloro-2-(1-piperazinyl)-monohydrochloride.

4.1.1. The ref. '397 differs from the instant compounds by not having N of instant -NR9, and also the -L-A component is absent.

4.1.2. The other ref. Page et al(Chemical Abstract DN 129:224913, also cited as ACS, Inorganic Chemistry, 367/17,4452-4459(1998) teaches quinoxaline, 6,7-dichloro-2,3-di-2-quinoliny-.

Page differs from the instantly claimed compounds by not having bridged similar to instant -L-A & -M-B.

Neither Englehardt nor Page indicate or suggest to arrive at the allowable subject matter of invention of Group III.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhaker Patel, D.Sc. Tech., whose telephone number is (703) 308 4709.

The examiner can normally be reached on Monday thru' Friday from 8:30 AM to 5:00 PM.



If attempts to reach the examiner by the phone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah can be reached at (703) 308 4716 or Sr. Examiner Mr. Richard Raymond at (703)308 4523.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

Any inquiry of general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308 1235.

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November 18, 2003



*Mukund J. Shah*  
**Mukund Shah**  
**Supervisory Patent Examiner**  
**Art Unit 1624**